

For caregivers of people 2 years and older
living with obesity due to Bardet-Biedl syndrome (BBS)

A guide to discussing treatment with your doctor

Obesity due to BBS has a unique cause



BBS is a rare genetic disease that affects the **key area of the brain that controls hunger or fullness called the hypothalamus**



Many people with BBS **experience early-onset obesity** that starts at a young age, even as young as 2 years



People living with BBS may also experience **constant, hard-to-control hunger, called hyperphagia**

IMCIVREE is the first and only FDA-approved treatment for people 2 years and older with obesity due to BBS to help them lose weight and keep the weight off.

Visit bbs.IMCIVREE.com or scan the QR code for more information



Review the steps on the next page as you start the conversation with your doctor about whether IMCIVREE may be right for your loved one.

What is IMCIVREE?

IMCIVREE is a prescription medicine used in adults and children 2 years of age and older with obesity due to Bardet-Biedl syndrome (BBS) to help them lose weight and keep the weight off.

IMCIVREE is not for use in people with the following conditions because it may not work:

- Other types of obesity not related to BBS or other FDA-approved uses of IMCIVREE, including obesity associated with other genetic conditions and general obesity

It is not known if IMCIVREE is safe and effective in children under 2 years of age.

IMPORTANT SAFETY INFORMATION

Do not use IMCIVREE if you have had a serious allergic reaction to it or any of its ingredients. Serious allergic reactions, including anaphylaxis, can happen.

Please see full [Prescribing Information](#) and [Patient Information](#), as well as Important Safety Information throughout.

Tips to support a productive conversation

1 **PREPARE for your loved one's appointment by writing down your thoughts beforehand.**

Consider noting the following:

- Your loved one's current weight management plan and treatments (if applicable)
- Challenges you or your loved one may have with managing hunger, thoughts of food, and food-seeking behaviors
- The effects of obesity and constant, hard-to-control hunger on your loved one's everyday life: **the more specific you are about how their obesity and hunger affects them, the better**

2 **ASK QUESTIONS to guide the conversation.** Some suggestions are included on the next page

3 **REPEAT the doctor's answers in your own words to make sure you are understanding them correctly.**

BE OPEN with your loved one's doctor when talking to them. You are your loved one's best advocate

ACT EARLY: Treating obesity due to BBS with IMCIVREE can help people lose weight and keep the weight off. In clinical trials, IMCIVREE reduced BMI and helped reduce severity of obesity

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Before you use IMCIVREE, tell your healthcare provider about all your medical conditions, including if you:

- Have or have had areas of darkened skin, including skin discoloration (hyperpigmentation)
- Have or have had depression, or suicidal thoughts or behavior
- Have kidney problems
- Are pregnant or planning to become pregnant. Losing weight while pregnant may harm your unborn baby. Your healthcare provider may stop your treatment with IMCIVREE if you become pregnant. Tell your healthcare provider if you become pregnant or think you might be pregnant during treatment with IMCIVREE

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Ask your loved one's doctor about IMCIVREE

IMCIVREE is the first and only treatment that targets a root cause of obesity and hunger due to BBS in people 2 years and older.



Starting the conversation

I recently heard about a treatment for obesity due to BBS called IMCIVREE, and I am interested in learning more.

- Do you think IMCIVREE might be an option for my loved one?
- Which specialists should I speak to about IMCIVREE?

How IMCIVREE works

- How does IMCIVREE work to treat obesity due to BBS?
- Can IMCIVREE help reduce weight?
- How is IMCIVREE different from other weight-loss medications?
- What are the possible side effects with IMCIVREE?

How to take IMCIVREE

- What can I expect with daily IMCIVREE injections?
- *[If you are caring for a young child]* How can I help my young child sit through an injection?
- Are there resources I can use to help my loved one with their first few injections?

Getting started with IMCIVREE

- How quickly will IMCIVREE help reduce weight and hunger?
- Is long-term IMCIVREE treatment important for the management of obesity due to BBS?

If you still have questions after your appointment, you may follow up with your loved one's doctor.



Rhythm
InTune
Support made personal

Whether you're learning about BBS, preparing for a visit, or managing daily routines, a Rhythm InTune Patient Education Manager (PEM)* can provide resources, education, and information. Visit [RhythmInTune.com](https://www.RhythmInTune.com) or scan the QR code



*Patient education managers are employees of Rhythm Pharmaceuticals and do not provide medical care or advice. We encourage you to always speak to your healthcare provider regarding your medical care.

Important Safety Information (Cont'd)

- Are breastfeeding or plan to breastfeed. It is not known if IMCIVREE passes into your breast milk. You should not breastfeed during treatment with IMCIVREE
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IMCIVREE[®]
(setmelanotide) injection

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Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

See the detailed Instructions for Use that come with your IMCIVREE to learn how to prepare and inject IMCIVREE, and how to properly throw away (dispose of) used syringes and needles.

What are the possible side effects of IMCIVREE?

IMCIVREE may cause serious side effects, including:

- **Male and female sexual function problems.** IMCIVREE can cause an erection that happens without any sexual activity in males (spontaneous penile erection) and unwanted sexual reactions (changes in sexual arousal that happen without any sexual activity) in females. If you have an erection lasting longer than 4 hours, get emergency medical help right away
- **Depression and suicidal thoughts or actions.** You or a caregiver should call your healthcare provider right away if you have any new or worsening symptoms of depression, suicidal thoughts or behaviors, or any unusual changes in mood or behavior
- **Serious allergic reactions.** Stop taking IMCIVREE and get medical help right away if you have any symptoms of a serious allergic reaction including: swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; rapid heartbeat
- **Increased skin pigmentation, darkening of skin lesions (moles or nevi) you already have, and development of new skin lesions.** These changes happen because of how IMCIVREE works in the body and will go away when you stop using IMCIVREE. You should have a full body skin exam before starting and during treatment with IMCIVREE to check for skin changes

The most common side effects of IMCIVREE include darkening of the skin, injection site reactions, nausea, headache, diarrhea, stomach pain, vomiting, depression, and an erection that happens without any sexual activity in males.

These are not all the possible side effects of IMCIVREE. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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